



April 10, 2014

An Open Letter to the Cancer Community Regarding Community Clinical Trials

Dear Colleagues,

As you are aware, the National Cancer Institute (NCI) is in the process of combining its two community-based research networks to create a single network that builds on the strengths of the Community Clinical Oncology Program/Minority-Based Community Clinical Oncology Program (CCOPs) and the NCI Community Cancer Centers Program (NCCCP). This network, the NCI Community Oncology Research Program (NCORP), will support a wide range of clinical research, including treatment-focused as well as cancer prevention and control-based clinical trials; population-based studies; and behavioral, health services, and outcomes research. It will encompass community-based cancer specialty organizations in the same manner as have the CCOPs and NCCCP, and will work closely with the National Clinical Trials Network (NCTN).

The transition to any new large clinical research structure is never easy either for the agency administering it or for those people and institutions applying to participate in it. The creation of the NCORP is no exception. Some of the difficulties are easily mitigated but others require greater efforts to ensure that the fundamental principles and values of clinical research are upheld. NCI remains fully committed to these principles, most especially our obligation to patients.

Current NCI grantees conducting community-based clinical research have voiced concerns about the maintenance of funding between the end of the current round of annual CCOP awards (June 1, 2014) and the start of the NCORP (now estimated to be August 1, 2014). With Fiscal Year 2014 budgets now in place, our grantees can be assured that NCI will fund all CCOPs at their current levels during this period. While this was always our intention, this has not been clearly communicated. Furthermore, currently funded investigators should continue the active, uninterrupted accrual of patients to new or ongoing clinical trials during this interval. As in the past, full funding for all research activities required to carry out approved studies will be provided.

Those CCOP/MB-CCOP institutions that successfully compete to become NCORP members should have a seamless stream of funding as the new consortium structure commences. NCI will work with sites that either do not successfully compete for an NCORP award or choose not to transition into the new network. NCI will make funds available, as necessary, to assist these sites to implement their affiliation with another site or to carry out the process of closing their NCI-supported activities. For those sites, decisions will be made on a case-by-case basis, in accord with factors such as accrual rates and number of patients in follow up. NCI remains committed to every patient

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enrolled in a clinical trial and will ensure that they continue to have the opportunity to receive the full benefit of those trials.

The CCOPs and MB-CCOPs, including their dedicated physicians and staff, have played an essential role in the national clinical trials enterprise. An effective transition into NCORP, along with the continued care of patients, will be an important measure of the new network's success. We must work together to adapt swiftly and effectively to achieve the goals of the new system— namely, to take advantage of recent advances in our understanding of cancer and to bring new knowledge into clinical trials conducted in the community. Our patients deserve nothing less.

Harold Varmus, M.D.
Director
National Cancer Institute